

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Masato FUJIOKA et al.

Title: THERAPEUTIC AGENTS FOR INNER EAR DISORDERS  
CONTAINING AN IL-6 ANTAGONIST AS AN ACTIVE  
INGREDIENT

Appl. No.: Unassigned

International 3/24/2005

Filing Date:

371(c) Date: Herewith

Examiner: Unassigned

Art Unit: Unassigned

Confirmation Unassigned  
Number:

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to  
Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being  
submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not  
intended as an admission that such document constitutes prior art against the claims of the  
present application or that such document is considered material to patentability as defined in  
37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be

appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the date of entry of the national stage as set forth in 37 CFR §1.491.

**RELEVANCE OF EACH DOCUMENT**

All of the documents listed on the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding International application. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner. An English-language abstract of the foreign-language document has been provided.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

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By \_\_\_\_\_

*MDK*

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Date September 22, 2006

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**10/593776**  
**IAP9 Rec'd PCT/PTO 22 SEP 2006**

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00) through 10/31/2002. OMB 0651-0031  
 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Date Submitted: September 22, 2006 <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Sheet	1	of	1	Application Number	Unassigned
				Filing Date	Herewith
				First Named Inventor	Masato FUJIOKA
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	053466-0420

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
A1	2001/0004456	A1	Tobinick	06/21/2001	

<b>UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Application Document		Name of Patentee or Applicant of Cited Document	Filing Date of Cited Document MM-DD-YYYY
		Serial Number	Kind Code <sup>2</sup> (if known)		

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY
		Office <sup>3</sup>	Number <sup>4</sup>		
A2	WO	92/19759		Chugai Seiyaku Kabushiki Kaisha	11/12/1992

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			
		T <sup>6</sup>			
	A3	HIRATA, Yuuichi et al., "Characterization of IL-6 Receptor Expression by Monoclonal and Polyclonal Antibodies", The Journal of Immunology, 1989, Vol. 143, No. 9, pgs. 2900-2906.			
	A4	MATSUDA, Tadashi et al., "Establishment of an Interlukin 6 (IL 6)/B Cell Stimulatory Factor 2-dependent Cell Line and Preparation of Anti-IL6 Monoclonal Antibodies", Eur. J. Immunology, 1988, Vol. 18, No. 6, pgs. 951-956.			
	A5	SATOH, Hitoshi et al., "Tumor Necrosis Factor- $\alpha$ , an Initiator, and Etanercept, an Inhibitor of Cochlear Inflammation", Laryngoscope, 2002, Vol. 112, No. 9, pgs. 1627-1634.			
	A6	TAMURA, Tatsuya et al., "Soluble Interleukin-6 Receptor Triggers Osteoclast Formation by Interleukin 6", Proc. Natl. Acad. Sci, 1993, Vol. 90, pgs. 11924-11928.			

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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